



March 5, 2009

Great Lakes and Environment Committee  
Lansing, Michigan

Re: HB 4402 – Restriction on the use of Lindane

Dear Representatives,

The Michigan Environmental Council supports HB 4402, which is a common sense step for Michigan to take to better protect Michigan's children from a toxic chemical. MEC supports this bill for both environmental and health concerns.

MEC is greatly concerned about the environmental impacts of Lindane in both the Great Lakes and in the larger global environment. According to the World Health Organization, "[L]indane is distributed all over the world and can be detected in the air, water, soil/sediment, aquatic and terrestrial organisms, and in food." [1]. The EPA notes that lindane and related isomers are mobile in the environment and, through long-range atmospheric transport, are deposited in the Arctic, where they have historically been among the most abundant organochlorine contaminants in the Arctic Ocean. [2].

The World Health Organization notes that bioconcentration of lindane occurs rapidly in microorganisms, invertebrates, fish, birds, and man, but that elimination can also occur rapidly when exposure is discontinued [1]. The discontinuation of agricultural Lindane will undoubtedly reduce the amount of Lindane found in our waters; however, we must look to reduce our Lindane usage as much as possible to truly eliminate this hazard from our water and the remaining source is pharmaceutical Lindane.

MEC believes that the restriction on Lindane use proposed in this legislation is a sensible step to both reduce Lindane use and to make sure than Lindane is being used in the safest manner possible. Michigan has already taken steps, through its Medicaid program to reduce pharmaceutical Lindane usage by requiring prior authorization for Lindane prescriptions. According to Michigan Medicaid pharmacy data, the average number of Lindane prescriptions averaged 236 paid claims in the ten months before this policy took effect (January through October 2004). After this policy, the average number of paid Lindane prescription Medicaid claims was reduced to 8.5 per month (November 2004 through January 2008).

Michigan is not alone in taking this step. At least 30% of states have restricted Lindane usage through their Medicaid programs. These restrictions range from listing Lindane as a non-preferred medication, which makes it a more expensive treatment option, to only approving a Lindane prescription of other treatment alternatives have been exhausted and the prescription of lindane meets the FDA guidelines. These restrictions limit when Lindane can be prescribed. The restriction put forward in HB 4402 would limit where Lindane can be used – we do not think that limiting where Lindane can be used is somehow more restrictive than when Lindane can be used.



Although Michigan has taken an important step to protect a segment of its population from the toxic effects of pharmaceutical Lindane, Michigan citizens are still experiencing adverse side effects from Lindane. Michigan's poison control centers are still receiving calls related to Lindane lotion and shampoo. Between January 2005 and June 2006, the poison control center at Children's Hospital in Detroit recorded 22 separate cases involving Lindane exposure. The ages of those exposed ranged from 11 months to 59 years. It is important to note that 4 cases (18%) involved children under 2 years of age and 9 (41%) involved children under 10 years of age. It is especially important to note that these cases happened after the FDA guidelines were issued that strongly recommended against use of Lindane products on anyone weighing under 110 pounds.

So, how will the restriction proposed in HB 4402 better protect Michigan's children from Lindane exposure? First, the current restriction for prescriptions is only in place for those on Medicaid – the same protection does not apply to those with private insurance or no insurance. HB 4402 will extend protection to all Michigan's citizens by encouraging all physicians to adhere to the FDA guidelines regarding pharmaceutical Lindane use.

Second, most of the adverse side effects of pharmaceutical Lindane have been a result of misuse of the product. Common misuses of the product include using the medication more than once, even though it is dispensed in a single-dose container, and using on another family member for whom the medication was not prescribed. Requiring Lindane products to be used only under the supervision of a physician will all but eliminate this misuse.

Finally, requiring Lindane to be used only under physician supervision will mean the immediate availability of medical personnel and facilities in the case of an adverse event. While the FDA has documented that most adverse side effects occur with misuse of Lindane, there have also been documented cases of adverse events when a Lindane product has been used correctly. As noted in the FDA Warning Letter sent to Morton Grove in December 2007, approximately 20% of cases of serious adverse outcomes reported use of lindane according to package direction. Given the seriousness of potential adverse events, it is logical that the medication be used only in an environment where medical care can take place immediately.

MEC supports HB 4402 fully and sees it as an important and logical step for Michigan to take to protect its waters and environment, children and citizens from this toxic chemical.

Sincerely,

James Clift, Policy Director

1. International Programme on Chemical Safety, *Lindane (Gamma-HCH) Health and Safety Guide*, Health and Safety Guide No. 54, World Health Organization. Accessed online on April 25, 2008 at <http://www.inchem.org/documents/hsg/hsg/hsg054.htm>
2. U.S. Environmental Protection Agency, *Lindane and Other HCH Isomers – EPA Risk Assessment Fact Sheet*. Published February 8, 2006. Accessed online on April 25, 2008 at [http://www.epa.gov/pesticides/reregistration/REDs/factsheets/lindane\\_isomers\\_fs.htm](http://www.epa.gov/pesticides/reregistration/REDs/factsheets/lindane_isomers_fs.htm)



**Frequently Asked Questions (FAQs) about HB 4402, which would restrict pharmaceutical use of the toxic chemical lindane on those with lice and scabies.**

- Q. Does HB 4402 ban the use of products containing lindane in Michigan, as has been done in 53 countries and the state of California?
- A. **No.** HB 4402 requires that lindane-containing products be used only under the direct supervision of a physician in his or her office. This restriction will help ensure that **this toxic product is being used as currently directed by the FDA** and that medical staff can immediately respond to any adverse neurological side effects. Other states and other countries, have or are pursuing more complete bans on lindane.
- Q. What uses are currently allowed in Michigan for lindane?
- A. Lindane **cannot be used in agriculture, in veterinary medicine or in the military** in Michigan or any other U.S. state except California<sup>i</sup>. The only remaining use is in pharmaceuticals that are applied directly to children's (or adults') heads or bodies.
- Q. What precedent might be set by imposing a restriction on a pharmaceutical?
- A. The Michigan Medicaid program already requires prior approval of lindane prescriptions before approving a claim, so lindane use is already somewhat restricted. The Legislature would be **responding to the request of the medical, health and environmental community** for the further restriction of this particular pharmaceutical. Lindane has such a toxic profile that the Michigan Chapter of the American Academy of Pediatrics and seven other major health and medical organizations are calling for a full ban and will support the current compromise bill<sup>ii</sup>. **Medical professionals are not asking the Legislature to restrict any other pharmaceutical.**
- Q. Is lindane pollution a problem in Michigan's waterways, including the Great Lakes? What is the EPA's view of lindane?
- A. According to the EPA, lindane is a **"bioaccumulative chemical of concern"**<sup>iii</sup> in the **Great Lakes, an "extremely hazardous substance"**<sup>iv, v</sup>, and a **"priority pollutant"** under the Clean Water Act<sup>vi</sup> "for the protection of aquatic life and human health in surface water..."<sup>vii</sup> Lindane has been **found in open waters across the Great Lakes**, including being "commonly found" in Lake Huron,<sup>viii</sup> and in sediments in the Lake St. Clair watershed,<sup>ix</sup> among other places. Lindane has been found annually in the tissues of bivalves throughout the Great Lakes.<sup>x</sup> **The EPA has no authority to take direct action** against lindane in pharmaceuticals since this is the FDA's jurisdiction. All uses of lindane under the jurisdiction of EPA have already been withdrawn.
- Q: Isn't the main problem with lindane its agricultural use?



A: Lindane is **no longer used for agriculture in the U.S.** According to the Los Angeles County Sanitation Authority, wastewater contamination with pharmaceutical lindane was the driving force behind California's ban on lindane.<sup>xi</sup> The FDA's strong concerns about lindane – and those of Michigan health professionals – are because of its medical use on children.

Q. What was the effect of California's lindane ban?

A. Lindane went from above California's standard of 19ppt for existing or potential drinking water sources **to virtually undetectable levels within four years of the ban.** Calls to California's Poison Control Centers regarding lindane were reduced from 135 per 100,000 calls to 2 per 100,000 calls. There was **no negative health effect** of California's ban of pharmaceutical lindane including no evidence of lice or scabies outbreaks. Most physicians were aware and supportive of the California ban; only a handful of complaints—mainly from older, non affiliated doctors—were recorded<sup>xii</sup>.

Q. Isn't the Food and Drug Administration (FDA) responsible for regulating lindane? Why should the Legislature get involved?

A. FDA has the responsibility to regulate pharmaceuticals; however, it is the state Legislature's responsibility to protect Michigan's children and its unique natural resources. Lindane use, and resultant adverse effects, has resulted in multiple calls to Michigan's Poison Control Centers<sup>xiii</sup>. HB 4402 would ensure that FDA guidelines, which advise physicians to use lindane only as a second line therapy without re-application, are followed by both physicians and patients<sup>xiv</sup>. **The state's major medical and health associations** – including the Michigan Chapter of the American Academy of Pediatrics and the Michigan Nurses Association – **are advocating for this bill** in part because it is in line with FDA guidelines.

Q. What are the FDA recommendations for the use of lindane shampoo and lotion?

A. The FDA has issued a "black box warning" and **taken unusually strong action** against the use of lindane. The FDA explicitly recommends in its Public Health Advisory issued March 2003 and its Questions and Answers About Lindane:

- Lindane as a second-line therapy to be used only **when other treatment alternatives have failed or cannot be tolerated by the patient;**<sup>xv</sup>
- Lindane products are to be used with **caution in patients who weigh less than 110 pounds (50 kilograms).**<sup>xvi</sup>
- Lindane products are not recommended for use on infants and are contraindicated in premature infants.<sup>xvii</sup>
- Elderly individuals are at higher risk for developing seizures and other adverse outcomes from lindane use.



- **Only a single treatment of lindane should be used even if itching continues.** The FDA states that it is unclear how soon after applying a first dose that a second dose of lindane can be safely applied.
- Lindane products should not be used by anyone with a seizure disorder (convulsions, fits) or who has ever had a seizure, especially seizures that have been hard to control.
- Lindane products should not be used if a patient has open or crusted sores (scabby sores) on the skin around the head and neck or broken skin in the treatment area.
- Lindane products should not be used on patients with other skin conditions, such as psoriasis or atopic dermatitis.
- Lindane products should not be used by women who are breast feeding because lindane can be absorbed into breast milk and transferred to an infant. Lindane lotion on a mother's skin can also be absorbed by an infant that comes in contact with her.

Q. What does the Michigan Department of Community Health (MDCH) say about lindane?

A. The **MDCH does not recommend using lindane** for lice or scabies and **supports HB 4402.**<sup>xviii, xix</sup>

Q. Given the very strong support from the state's medical and health community and Department of Community Health, who opposes this bill?

A. Based on testimony given so far, the only organization opposed to this bill is **Morton Grove Pharmaceuticals, an Indian-owned company** that is the sole provider of lindane pharmaceutical products in the U.S. Their consultants are testifying in opposition to the bill. At least one pediatric dermatologist in Michigan has also expressed concerns, although his position seems contrary to that of the American Academy of Dermatology on scabies, which states "**Lindane should not be used on infants, small children, pregnant or nursing women.**"<sup>xx</sup> However, HB4402 would allow doctors who prefer to use lindane to do so.

Q. Are lindane shampoos and lotions always safe when used in accordance with directions?

A. **No.** According to the FDA, there are cases documented in the FDA Adverse Event Warning System, where the product was used correctly and adverse side effects still occurred. While the most serious adverse events occurred when a lindane product was used inappropriately, children and elderly patients remain especially susceptible to the toxic effects of lindane even when used properly.<sup>xxi</sup> As noted in the FDA's Public Health Advisory on Lindane issued in March 2003, "Rates of adverse events cannot be calculated from this system and underreporting is presumed, especially for older products like Lindane Lotion and Shampoo."



Q. How effective is lindane? Will we see more lice or scabies outbreaks if lindane use is restricted?

A. According to peer-reviewed studies, **alternatives to lindane are more or equally effective for the treatment of head lice**<sup>xxii</sup>. Evidence in California shows that not using lindane does not lead to increased outbreaks of lice or scabies<sup>xxiii</sup>. In fact, lindane's use has been declining for years and many medical and nursing schools are no longer teaching its use.

Q. Would restricting lindane products lead to outbreaks of serious diseases?

A. Despite claims from those promoting the use of lindane products in treating lice and scabies, there is **no need to be concerned about outbreaks of diseases** such as trench fever, relapsing fever, and typhus carried by lice. No cases of relapsing fever or trench fever have ever been reported to the Michigan Department of Community Health. Relapsing fever, which is transmitted by body lice and not head lice or pubic lice, has not been reported in the U.S. since 1906. Endemic relapsing fever is confined to the Western U.S. and is transmitted by ticks, not lice. There were three reported cases of typhus in Michigan between 2002 and 2006, but it is unclear whether these were murine typhus, which is transmitted by fleas. Regardless, **head lice and pubic lice, which are what lindane products can be prescribed for, do not transmit typhus or any other infectious microbes.**<sup>xxiv</sup>

Q: Why did the FDA order Morton Grove Pharmaceuticals to “immediately cease the dissemination of violative promotional materials for lindane shampoo” on December 13, 2007?

A: The FDA sent **an official, very strongly worded “Warning Letter” to Morton Grove Pharmaceuticals**<sup>xxv</sup>

The FDA wrote:

*“The [Morton Grove] websites and newsletter are **misleading in that they omit and/or minimize the most serious and important risk information associated with the use of Lindane Shampoo**, particularly in pediatric patients; include a misleading dosing claim; and overstate the efficacy of Lindane Shampoo. In particular, Lindane Shampoo is plainly labeled as second line treatment, **suitable only when other, safer treatments fail or are not tolerated**. The materials convey little sense of this limitation and little about the **magnitude and nature of the risks associated with the drug**. The materials appear to represent an attempt to **downplay the significant risks***

*associated with Lindane Shampoo use and encourage wider use, with less care, than is appropriate under approved labeling.”* [Emphasis added.]

The FDA further states:

*“We are very concerned about the potential for significant negative health*



*consequences in children who use Lindane Shampoo because you are promoting Lindane Shampoo as being safer and more effective for pediatric patients than has been demonstrated by substantial evidence or substantial clinical experience, despite the boxed warning in Lindane Shampoo's FDA-approved product labeling (PI), and FDA's March 2003 Public Health Advisory and Talk Paper describing the risk of severe neurotoxicity in patients, including children, who weigh less than 110 pounds (50 kilograms)."* [Emphasis added.]

And further:

*"In fact, as stated in its PI, Lindane Shampoo should be used with caution in children because its use has been associated with seizures and death, and because of this risk it is second line treatment. Neither this risk nor any other risk information for the drug is disclosed anywhere on this [Morton Grove's] website."* [Emphasis added.]

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- <sup>i</sup> United States Environmental Protection Agency. Lindane Voluntary Cancellation and RED Addendum Fact Sheet: Registrants' Cancellation Request and EPA's Lindane RED Addendum. July 2006. Accessed on 8-17-06 at: [www.epa.gov/oppsrrd1/REDs/factsheets/lindane\\_fs\\_addendum.htm](http://www.epa.gov/oppsrrd1/REDs/factsheets/lindane_fs_addendum.htm).
- <sup>ii</sup> Michigan Chapter of the American Academy of Pediatrics?????
- <sup>iii</sup> U.S. Environmental Protection Agency. Great Lakes Initiative, Bioaccumulative Chemicals of Concern Affected by the ban on Mixing Zones in the Great Lakes. Accessed 1-8-07 at: [www.epa.gov/waterscience/gli/mixingzones/chemicals.html](http://www.epa.gov/waterscience/gli/mixingzones/chemicals.html).
- <sup>iv</sup> U.S. Environmental Protection Agency. Chemical Emergency Preparedness and Prevention. Background. Accessed 1-8-07 at: <http://yosemite.epa.gov/oswer/ceppoehs.nsf/content/BackGround>.
- <sup>v</sup> U.S. Environmental Protection Agency. Alphabetical Order List of Extremely Hazardous Substances (Section 302 of EPCRA). Accessed 1-8-07 at: [http://ypse.ote.epa.gov/oswer/ceppoehs.nsf/EHS\\_Profile?openform](http://ypse.ote.epa.gov/oswer/ceppoehs.nsf/EHS_Profile?openform).
- <sup>vi</sup> U.S. Environmental Protection Agency. Water Quality Criteria. Accessed 1-8-07 at: [www.epa.gov/waterscience/criteria/wqcriteria.html](http://www.epa.gov/waterscience/criteria/wqcriteria.html).
- <sup>vii</sup> U.S. Environmental Protection Agency. Great Lakes Initiative, Fact Sheet: Final Regulation to Ban Mixing Zones in the Great Lakes. Accessed 1-8-07 at: [www.epa.gov/waterscience/gli/mixingzones/finalfact.html](http://www.epa.gov/waterscience/gli/mixingzones/finalfact.html).
- <sup>viii</sup> Environment Canada and US Environmental Protection Agency. State of the Great Lakes 2007.
- <sup>ix</sup> U.S. Geological Service in cooperation with the Lake St. Clair Regional Monitoring Project. Areal Distribution and Concentration of Contaminants of Concern in Surficial Streambed and Lakebed Sediments, Lake St. Clair and Tributaries, Michigan, 1990-2003.
- <sup>x</sup> National Oceanic & Atmospheric Administration (NOAA). Mussel Watch. Accessed 5-4-08 at: [http://www8.nos.noaa.gov/cit/nsandt/ana\\_conc\\_dist\\_analysis.aspx?program=MW](http://www8.nos.noaa.gov/cit/nsandt/ana_conc_dist_analysis.aspx?program=MW).
- <sup>xi</sup> LA County Sanitation board???????
- <sup>xii</sup> Humphreys et al. Outcomes of the California Ban on Pharmaceutical Lindane: Clinical and Ecologic Impacts. Environmental Health Perspectives 116, no. 3 (2008): 297-302.
- <sup>xiii</sup> MI Poison Control?????????
- <sup>xiv</sup> U.S. Food and Drug Administration (FDA). Center for Drug Evaluation and Research. Public Health Advisory: Safety of Topical Lindane Products for the Treatment of Scabies and Lice. 2003. Accessed 5-5-08 at: [www.fda.gov/cder/drug/infopage/lindane/lindanePHA.htm](http://www.fda.gov/cder/drug/infopage/lindane/lindanePHA.htm).
- <sup>xv</sup> U.S. Food and Drug Administration (FDA). Center for Drug Evaluation and Research. Public Health Advisory: Safety of Topical Lindane Products for the Treatment of Scabies and Lice. 2003. Accessed 5-5-08 at: [www.fda.gov/cder/drug/infopage/lindane/lindanePHA.htm](http://www.fda.gov/cder/drug/infopage/lindane/lindanePHA.htm).
- <sup>xvi</sup> Ibid
- <sup>xvii</sup> Ibid
- <sup>xviii</sup> Michigan Department of Community Health. Michigan Head Lice Manual. Version 1.0. July 2004. Accessed 12-22-06 at: [www.michigan.gov/documents/Final\\_Michigan\\_Head\\_Lice\\_Manual\\_103750\\_7.pdf](http://www.michigan.gov/documents/Final_Michigan_Head_Lice_Manual_103750_7.pdf).
- <sup>xix</sup> Michigan Department of Community Health. Scabies Prevention and Control Manual. Version 1.0. May 2005. Accessed 12-22-06 at: [www.michigan.gov/documents/BHS\\_NHM\\_Michigan\\_Scabies\\_Prevention\\_and\\_Control\\_Manual\\_131983\\_7.pdf](http://www.michigan.gov/documents/BHS_NHM_Michigan_Scabies_Prevention_and_Control_Manual_131983_7.pdf).
- <sup>xx</sup> American Academy of Dermatology. Scabies. Accessed 4-29-08: [http://www.aad.org/public/publications/pamphlets/common\\_scabies.html](http://www.aad.org/public/publications/pamphlets/common_scabies.html)



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- <sup>xxi</sup> U.S. Food and Drug Administration (FDA). Center for Drug Evaluation and Research. Public Health Advisory: Safety of Topical Lindane Products for the Treatment of Scabies and Lice. 2003. Accessed 5-5-08 at: [www.fda.gov/cder/drug/infopage/lindane/lindanePHA.htm](http://www.fda.gov/cder/drug/infopage/lindane/lindanePHA.htm).
- <sup>xxii</sup> Meinking et al. Comparative efficacy of treatments for pediculosis capitis infestations - Update 2000. Archives of Dermatology 137, no. 3 (2001): 287-292.
- <sup>xxiii</sup> Humphreys et al. Outcomes of the California Ban on Pharmaceutical Lindane: Clinical and Ecologic Impacts. Environmental Health Perspectives 116, no. 3 (2008): 297-302.
- <sup>xxiv</sup> Letter from Dr. Bill Weil to Representative Rebekah Warren: April 3, 2008.
- <sup>xxv</sup> FDA Warning Letter to Morton Grove Pharmaceuticals. Accessed 3-12-08: [http://www.fda.gov/foi/warning\\_letters/s6604c.htm](http://www.fda.gov/foi/warning_letters/s6604c.htm)